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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,498	07/15/2005	Seiji Morii	TIP05-1194	5310

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/542,498	MORII ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Status of Claims:

Claims 1-7 are pending.

Claims 1-7 have been rejected.

DETAILED ACTION

1. Claims 1-7 are under consideration in this Office Action.

Priority

2. It is noted that this application is a 371 of PCT/JP03/16474 (12/22/03), which has a foreign priority document, Japan 20038023 filed on 01/16/2003.

Drawings

3. None.

Claim Objections

Claim 1 is objected to because of the following informalities: In claim 1 , the term " comprising " is absent. This term is essential because other unspecified limitations can not be added with that term. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, the phrase" a raw material containing a racemic amine and the optically active diacyltartaric acid " is recited. This expression is vague and indefinite because the phrase "containing" would mean that there are other unspecified material present in the raw material; the skilled artisan would not figure out what they are ; therefore, there is uncertainty as to what other components may be present in the raw material. Therefore, an appropriate correction is required.

In claim 7, the phrase" one isomer type" is recited. This expression is vague and indefinite because there is uncertainty as to what type of the isomer would exist in the diastereomer salt. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakie et al (JP3072446).

Sakie et al discloses the preparation of dibenzoyl-D-tartaric acid in the following example 5:

106.9g of the salt of (S)-1,2-diaminopropane and dibenzoyl-D-tartaric acid having an optical purity of 91%ee was added into 250ml of water, and then stirred for 1 hour at 70℃. After addition of the salt, the mixture was cooled to 30℃, taking 5 hours. The precipitated crystal was taken out through filtration and dried to obtain 94.4g of a salt of (S)-1,2-diaminopropane and dibenzoyl-D-tartaric acid. This salt was added into 205ml of 9% hydrocloric acid aqueous solution, taking 3 hours. The mixture was stirred for 1 hour, to precipitate dibenzoyl-D-tartaric acid were collected by filtration and rinsed with water. 56g of 50% sodium hydroxide aqueous solution was added into the filtrate and the rinsing liquid for basic solution, and then distilled in atmospheric pressure to obtain 15.3g of a fraction of 115-118 ℃. Water content of the obtained (S)-1,2-diaminopropane was 15%(yield 80%). The optical purity was 98%ee.

However, the instant invention differs from the prior art in that the optically active diacyltartaric acid is added beforehand in the acid aqueous solution; the amount of the optically active diacyltartaric acid is added from 0.05 to 3 wt % based on the wt of the acid aqueous solution ; the recycling the recovered optically active diacyltartaric acid into the optical resolution step.

With respect to the optically active diacyltartaric acid being added beforehand in the acid aqueous solution, the prior art is silent . However, it has been held that merely reversing the order of the steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. **Ex Parte Rubin,** 128 USPQ 440 (P.O.B.A. 1959). Cohn v. Comr .Patents, 251 F. supp. 437, 148 USPQ 486 (D.C. 1966). Therefore, it would have been obvious to the skilled artisan in the art to be reverse the steps as an alternative so as to find out which procedure would be an optimal one.

Regarding to the absence of teaching the added amount of the optically active diacyltartaric acid to the acid aqueous solution, the prior art is silent . However, the

limitation of a process with respect to pH, concentration, time ,speed does not impart patentability to a process when such values are those which would be determined by one of the ordinary skill in the art in achieving optimum operation of the process. The concentration in the resolution process is well-understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control the selectivity of the resolution process.

Concerning the lack of the recycling the recovered optically active diacyltartaric acid into the optical resolution step. This is directly related to the optimization process. In order to save the time and the economy of the process, it would have been obvious to the skilled artisan in the art to recycle the recovered optically active diacyltartaric acid into the optical resolution step.

Sakie et al expressly discloses the preparation of dibenzoyl-D-tartaric acid; it has been held that merely reversing the order of the steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. **Ex Parte Rubin,** 128 USPQ 440 (P.O.B.A. 1959). Cohn v. Comr .Patents, 251 F. supp. 437, 148 USPQ 486 (D.C. 1966). Therefore, it would have been obvious to the skilled artisan in the art to be reverse the steps as an alternative so as to find out which procedure would be an optimal one.

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakie et al (JP3223236).

Sakie et al discloses the preparation of di-p-toluoyl-D-tartaric acid in the following example 5:

> **99.8g of the salt of (S)-1,2-diaminopropane and di-p-toluoyl-D-tartaric acid having an optical purity of 97%ee was added into 205ml of 9% hydrocloric acid aqueous solution, taking 3 hours. After addition of the salt, the mixture was stirred for 1 hour, to precipitate di-p-toluoyl-D-tartaric acid were collected by filtration and rinsed with water. 56g of 50% sodium hydroxide aqueous solution was added into the filtrate and the rinsing liquid for basic solution, and then distilled in atmospheric pressure to obtain 15.3g of a fraction of 115-118℃. Water content of the obtained (S)-1,2-diaminopropane was 15%(yield 80%). The optical purity was 97%ee.**

However, the instant invention differs from the prior art in that the optically active diacyltartaric acid is added beforehand in the acid aqueous solution; the amount of the optically active diacyltartaric acid is added from 0.05 to 3 wt % based on the wt of the acid aqueous solution ; the recycling the recovered optically active diacyltartaric acid into the optical resolution step.

With respect to the optically active diacyltartaric acid being added beforehand in the acid aqueous solution, the prior art is silent . However, it has been held that merely reversing the order of the steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. **Ex Parte Rubin,** 128 USPQ 440 (P.O.B.A. 1959). Cohn v. Comr .Patents, 251 F. supp. 437, 148 USPQ 486 (D.C. 1966).

Therefore, it would have been obvious to the skilled artisan in the art to be reverse the steps as an alternative so as to find out which procedure would be an optimal one.

Regarding to the absence of teaching the added amount of the optically active diacyltartaric acid to the acid aqueous solution, the prior art is silent . However, the limitation of a process with respect to pH, concentration, time ,speed does not impart patentability to a process when such values are those which would be determined by one of the ordinary skill in the art in achieving optimum operation of the process. The concentration in the resolution process is well-understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control the selectivity of the resolution process.

Concerning the lack of the recycling the recovered optically active diacyltartaric acid into the optical resolution step. This is directly related to the optimization process. In order to save the time and the economy of the process, it would have been obvious to the skilled artisan in the art to recycle the recovered optically active diacyltartaric acid into the optical resolution step.

Sakie et al expressly discloses the preparation of di-p-toluoyl-D-tartaric acid; it has been held that merely reversing the order of the steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. **Ex Parte Rubin,** 128 USPQ 440 (P.O.B.A. 1959). Cohn v. Comr .Patents, 251 F. supp. 437, 148 USPQ

486 (D.C. 1966). Therefore, it would have been obvious to the skilled artisan in the art to be reverse the steps as an alternative so as to find out which procedure would be an optimal one.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh ,MS.D. , LAC.
Primary Examiner
Art Unit : 1625

9/X/06